FORUM OF END STAGE RENAL DISEASE NETWORKS

April 17, 2020

Dear CMS Colleagues,

Thank you for the opportunity to comment per our previous correspondences dated March 23, 2020 and April 3, 2020. We would like to acknowledge the great work by CMS related to the COVID-19 pandemic and ESRD patients. The Forum of ESRD Networks would like to again thank CMS for releasing waivers on telehealth services, documentation, reporting requirements, equipment, audits, and emergency preparedness in addition to expanding the Special Purpose Dialysis Facility designation and allowing for dialysis to be performed in nursing homes. All of these and other waivers that have been granted help support our efforts to care for our patients in these challenging times.

The Forum continues to work closely with the ESRD Networks to assist in the dissemination of information to providers and patients in support of the care of kidney patients and we appreciate the opportunity to relay additional comment to you about issues we are hearing from the networks related to how COVID-19 is affecting dialysis patients. We also offer potential solutions to help address some of these critical issues. Below we have listed a few comments and possible solutions:

Issue: In our comments to CMS dated March 23, we previously brought up the issue of ESRD facilities having difficulty transporting COVID + patients and PUI to and from their dialysis facilities from home. We continue to hear reports that this issue persists and seems to be worsening as more ESRD patients are becoming infected with COVID-19 over time. In many areas, local wheelchair van services that normally transport ESRD patients to and from their dialysis facilities are unable or unwilling to transport COVID+ patients or PUI. Many of these vehicles are not equipped to transport these patients, and many of the drivers do not have necessary PPE, or do not have the proper training or expertise to adequately protect themselves or other patients. In addition, in many areas Medicaid will not reimburse for transporting these patients in these wheelchair vans, so they are refusing to transport COVID + ESRD patients. For all of these reasons, Dialysis facilities are being forced to use ambulances to transport patients to and from dialysis. However, such transportation is often not covered by Medicaid or private insurance as the patients may be ambulatory or may not meet other clinical criteria for ambulance transportation.

It is critical that we continue to treat dialysis patients in dialysis outpatient facilities when they don't medically require hospitalization to help preserve resources in hospitals and help hospitals from being overwhelmed with COVID + patients that otherwise do not need to be hospitalized. Therefore, this issue of transportation is critical to solve given the above issues, in order to prevent COVID+ and PUI dialysis

patients who cannot obtain transportation to and from dialysis from either missing treatments leading to hospitalizations or being admitted to hospitals solely for their dialysis treatments.

Suggestion: We would suggest that CMS issue official guidance as soon as possible clarifying that COVID+ or PUI ESRD patients meet the clinical criteria for emergency ambulance transportation to and from home to their ESRD facility. This guidance should be publicized to hospitals and EMS services around the US. In addition, as we previously suggested in our comments on March 23, we would also recommend that both Medicare and Medicaid reimburse ambulance transfer of COVID + and PUI ESRD patients to and from their ESRD facility during this pandemic. We would also recommend that non-traditional sources of transportation such as military vehicles supported by the National Guard, or other emergency forms of transportation be employed as needed in areas where the incidence of COVID-19 cases are greatest and where the ability to transport ESRD patients to and from dialysis is most limited.

Issue: The Forum continues to hear reports of shortages of CRRT dialysis fluid and supplies, in addition to PD fluid and supplies, especially in areas with the greatest numbers of COVID-19 cases such as New York City. The vendors that supply these critical fluids for dialysis have allocated the amount of fluid being delivered to hospitals based on historical use of the hospital, despite a very large increase in demand for the fluid to help treat the many cases of AKI secondary to COVID-19. Despite the critical nature of dialysis to help preserve the lives of patients with AKI or ESRD, the shortage of dialysis supplies is not receiving the same national publicity as ventilator shortages. In addition, the large percentage of patients with COVID-19 in hospitals that develop AKI and require dialysis is not widely discussed or publicized. On a CMS call tonight, we heard from a New York City hospital that due to these shortages, dialysis treatments were needing to be shortened or skipped. This unfortunate situation may place these vulnerable hospitalized patients at increased risk of harm or death.

Suggestion: We would suggest that CMS help raise the importance of this issue to senior HHS and Government Officials to help preserve the lives of patients hospitalized with COVID-19 that develop AKI, or patients with ESRD who are hospitalized with COVID-19. This situation could be greatly improved if the vendors allowed these critical supplies to be reallocated from areas with lower numbers of hospitalized patients on dialysis to areas with greater numbers of COVID-19 patients requiring dialysis. In addition, we would recommend immediate emergency increased production and expedited delivery of these critical fluids and supplies under the Defense Production Act to meet the needs of hospitals around the US experiencing patient surges.

Issue: The Forum is aware that several hospitals and dialysis facilities in areas with a great number of COVID-19 cases are facing a shortage of healthy, qualified nurses and other dialysis staff to care for patients with AKI in the hospital setting, or ESRD in the hospital or outpatient dialysis setting. In many cases, staff members may be out of work sick themselves, or caring for ill family members. In addition, the great number of COVID+ patients in hospitals with AKI requiring dialysis in many cases, has exceeded the ability of current dialysis staff to provide dialysis. However, in some regions that have fewer cases of COVID-19 currently, the staffing is adequate to safely dialyze all the patients that require dialysis. Ideally, qualified dialysis staff could be deployed from areas that are adequately staffed to areas where they are needed the most. Although

some larger dialysis organizations may be able to internally redeploy staff to areas of need, hospital-based dialysis facilities, hospitals, and independent dialysis facilities likely do not have the same flexibility and adequate number of staff to do this. In some cases, licensing or credentialing issues may prevent nurses from working in certain states or areas on short notice.

Suggestion: We would suggest CMS works with states and large national organizations such as ANNA, in addition to LDOs, to help encourage redeployment of staff to areas where they are most needed. The entities that are involved in the recruitment and deployment of staff to hard hit areas should proactively identify those with dialysis skills. In addition, we would recommend that CMS assist in supporting a new initiative to rapidly train new dialysis nurses to assist in dialysis facilities and hospitals that may be experiencing staff shortages in their dialysis programs due to the COVID-19 pandemic.

Issue: The Forum greatly appreciates the clarification CMS issued that dialysis vascular access procedures should be considered essential and not elective procedures. Despite this clarification, the Forum is aware of multiple reports around the US of hospitals and Surgeons interpreting state or federal mandates as banning the performing vascular access procedures and thus, leaving ESRD patients with catheters as their only dialysis access and further reducing the possibility of transitioning patients to rapidly home thereby reducing their risk of COVID-19 exposure. This situation may place many ESRD patients at increased risk of morbidity or mortality due to use of catheters for their dialysis access during the COVID-19 pandemic. In addition, the increase in catheter use may set back the previous gains in recent years by the ESRD Networks and facilities in increased AVF prevalence rates and decreased catheter prevalence rates.

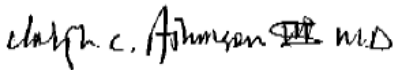
Suggestion: The Forum suggests that CMS release a more formal document clearly stating that vascular access procedures including AVF, AVG and PD catheter placement and interventions are essential procedures during the COVID-19 pandemic. The document should also state that these procedures must not be delayed, unless the current conditions in the local hospital are severe enough to preclude the ability to perform these procedures, or the supplies or staffing are inadequate to perform these procedures. This more formal guidance should be widely disseminated to hospitals and surgeons throughout the US.

Issue: The Forum has heard reports of state health departments performing onsite infection control surveys during the COVID-19 pandemic that have been disruptive to dialysis facilities. In many cases, the surveyors have used the scarce PPE present in the dialsyis facility during their surveys. In addition, the Forum has heard reports of large variability in these infection control surveys from state to state. In some cases, the surveyors focused on documentation issues, and other issues unrelated to infection control.

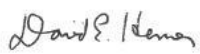
Suggestion: The Forum suggests that clear guidance from QSOG be issued to state survey agencies on how these infection control surveys should be conducted to minimize variability between states. Whenever possible, the Forum would suggest that infection control surveys be conducted by telephone or video conference. If the surveyors need to survey dialysis facilities in person, then the guidance should suggest that surveyors be sensitive to the upheaval that dialysis

facilities may be facing currently, and every effort should be made minimize disruption to the care of ESRD patients. In addition, guidance should suggest that surveyors bring their own PPE into facilties that they suveying.

Sincerely,



Ralph Atkinson III, MD
President, Forum of ESRD Networks



David Henner, DO
Chair, Forum Medical Advisory Council

Derek Forfang
Chair, Forum Kidney Patient Advisory Council